GUIDANCE for CFAR CLINICAL RESEARCH STUDIES

NIH Definition of a **Clinical Trial**- A prospective study of human subjects designed to answer questions about biomedical and behavioral interventions, e.g., drugs, treatments, or devices or new ways of using known treatments to determine whether they are safe and effective.

http://www.niaid.nih.gov/ncn/glossary/default2.htm#c

I. Studies that cannot be funded through the CFAR

- Studies involving new drugs, treatments, or devices, or off-label use of a licensed drug, are not allowed through the CFAR.

  These studies must go through the NIH R34 process.

II. Studies that can be funded via CFAR but require additional NIH review

- Studies involving **licensed drugs, treatments, or devices** (allowed on a case-by-case basis)
- Studies that are deemed **above minimal risk** by the Institutional IRB
- Studies involving **vulnerable populations**
  Studies involving **behavioral interventions** (above minimal risk)

  For studies falling in the above two research areas, please send completed CFAR Clinical Checklist.

III. Studies that do not require additional NIH review

Please include IRB approval letter in the annual progress report.

This guidance is based on the OHRP guidelines of research that would go through an expedited review procedure.

This may include research activities that present **no more than minimal risk t**o human subjects. Examples include but are not limited to the following:

- routine blood draws
- non-invasive procedures routinely employed in clinical
- practice (e.g. ultrasound, MRI)
- surveys, focus groups

For more information, please go to:
http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm